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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/619,142 07/19/00 KNOWLES

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HM12/0327

EXAMINER

KIM, V

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/619,142

Applicant(s)

KNOWLES, W. RAY

Examiner

Vickie Y. Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Status of Application

1. Acknowledgement is made of Declarations under Rule 131 and 132, filed Feb. 12, 2001.

Response to Arguments

2. Applicant's arguments filed Feb. 12, 2001 have been fully considered but they are not persuasive. Furthermore, applicant's declaration under 131 to antedate Bradbury et al's reference makes the new ground(s) of rejection necessitated.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 8-10, 12, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rajadhyaksha et al(US 5,482,965).

The claims 1-4 and 8-10 read on a composition comprising minoxidil or a testosterone blocker with a penetration enhancer.

Rajadhyaksha et al teach a topical composition comprising minoxidil or progesterone with a penetration enhancer; see example 18 and example 29. It is very clearly anticipated that topically composition containing either monoxidil or progesterone that is a species of testosterone blocker as said in claim 6, is benefiting by a penetration enhancer without side effect.

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It is noted that the preamble in claims 8-10 is not weighable because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Even if applicant's conception is earlier than Bradbury et al's, the claimed invention is not patentably distinct because it has been taught in other cited references. Rajadhyaksha et al (US 5,482,965) was included in previous PTO-892 (see paper no. 5).

Claims 12, 14 also properly included in this rejection because they read on a method of preventing or treating alopecia or maintaining hair using the composition containing minoxidil with a penetration enhancer. Rajadhyaksha et al teach a topical composition for promoting hair growth comprising minoxidil with a penetration enhancer; see example 18.

Thus the claims 1-4, 8-10, 12, 14 are maintained as rejected.

5. Claims 1-4, 8-10, 12-15, 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bazzano (US 5,183,817).

Bazzano (US'817) also teach all the critical elements (minoxidil and progesterone as active ingredient for hair growth, treating alopecia); see abstract and claims 24, 28, especially column 3-4 and 19-20. For the exemplified topical composition includes minoxidil/ethanol+propylene glycol; see column 24, formulation 1, 2. It is noted again that if the prior art structure is capable of performing the intended use, then it meets the claim. It is notoriously known in the art that a mixture of ethanol+propylene glycol is a commonly used

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penetration enhancer.(Applicant should consider the reference as a whole because claims 28, in fact, require minoxidil/ progesterone/ ethanol+propylene glycol. Also this penetration enhancer used in this patented reference, which is well documented and known in the state of the art should be acknowledged by applicant also. For the support for this examiner's position, however, see Mikulak et al(1998) "transdermal delivery and ...").

Thus the claimed subject matter is not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoke (US5,994,319) in view of Orentreich et al (US 5,053,403), .

Hoke (US'319) teach a synergistic compositions for stimulating hair growth(restoring hair) and preventing alopecia (hair loss), are using a composition of minoxidil in combination with an inhibitor of steroid 5-alpha reductase (antisense oligonucleotides).

Applicant's claims differ because they require progesterone.

It would have been obvious to one of ordinary skill in the art to substitute progesterone to antisense oligonucleotides when Hoke 's reference is modified with Orentreich et al because Orentreich et al teach progesterone is one of preferable 5-alpha reductase inhibitor.

Orentreich et al teach a method for preventing and treating male-pattern baldness, hirsutism, and sebaceous gland hypertrophy, using a composition comprising a 5-alpha reductase inhibitor such as progesterone via blocking testosterone conversion to it's most active metabolite DHT ; see column 1 and column 2.

One would have been motivated to do so, with reasonable expectation of success, because they have same biological pathway(working via same mechanism), especially progesterone is most active inhibitor and is proven for it's efficacy as well as it's safety, wherein possible side effects are well documented since it has been used in the art for long time.

It is noted that a pharmaceutical formulation with penetration enhancer, or adding sunscreen required by the dependent claims, is not considered to be critical because it is common practice which has been utilized by the skilled artisan in the state of the art as cited by many references in the art; see PTO-892. (e.g.; Bradbury et al ,US 6,124,362).

4. In response to applicant's response that there is no motivation to combine these two references, this examiner should point out that Hoke mentioned the inhibitors , particularly those that inhibit the conversion of testosterone to dihydrotestosterone, have shown effects on hair cycles, including inhibition of hair loss: see abstract. Since US'403 clearly stated that progesterone is preferred 5 alpha reductase inhibitor that is effectively used in male-pattern

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baldness, it is more that obvious to modify the composition by substituting progesterone, at the time the invention was made.

Conclusion

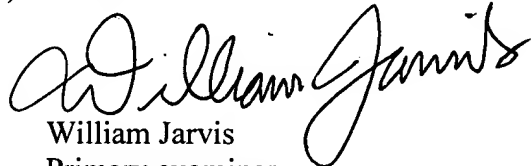
5. All the pending claims are maintained as rejected.
6. Applicant's amendment (131 declaration) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is (703) 305-1675 (Monday-Thursday: 7AM-6PM) and Fax number is (703) 308-7924.



Vickie Kim,
Patent examiner
March 14, 2001



William Jarvis
Primary examiner
Art unit 1614